



Tennessee Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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<http://tn.gov/health/topic/pharmacy-board>

Board Disciplinary Action Report

Tennessee Code Annotated (TCA) 68-1-114 requires the Tennessee Department of Health to issue a monthly media release listing all disciplinary actions taken by the health-related boards during the prior month. Information about disciplinary actions is available at <https://www.tn.gov/health/article/boards-disciplinary-actions#dars>. For more information on each action, click “License Verification” and enter the name of the person. When the results appear, click either “disciplinary action” or “adverse licensure action” in the right column. For the Tennessee Board of Pharmacy, the following actions were taken for the months of October, November, and December 2015.

October 2015

The following registrations were suspended for failure to pay student loans (RT = registered pharmacy technician).

- ◆ **Scott Kevin Bradford, RT**, Portland, TN
- ◆ **Patricia G. Cude, RT**, Manchester, TN
- ◆ **Kelly A. Dickerson, RT**, Knoxville, TN
- ◆ **Matthew Donio, DPh**, Mount Pleasant, TN
- ◆ **Patrick Lamar Hawkins, RT**, Smyrna, TN
- ◆ **Gabriella E. Hebert, RT**, Knoxville
- ◆ **Caroline L. Motley, RT**, Alcoa, TN
- ◆ **Catherine Pruett, RT**, Covington, TN
- ◆ **Kristi Lynn Russell, RT**, Knoxville
- ◆ **Antionette Seales, RT**, Nashville, TN
- ◆ **Courtney L. Smith, RT**, Nashville
- ◆ **Wanda Jane Smolik, RT**, Greenwood, IN
- ◆ **Michelle Nichole Lee Whitehead, RT**, Elizabethton, TN
- ◆ **Starr Williamson, RT**, West Memphis, AR
- ◆ **Tacora Shenise Wright, RT**, Nashville

November 2015

The following registrations were suspended for failure to pay student loans.

- ◆ **Sara C. Bond, RT**, Kingsport, TN
- ◆ **Lakesha S. Brooks, RT**, Gallatin, TN
- ◆ **Danita June Marsh, RT**, Shelbyville, TN
- ◆ **Cassandra Lynn Parker, RT**, Chattanooga, TN
- ◆ **Candy Gail Raye, RT**, Nashville
- ◆ **Adrian D. Smith, RT**, Memphis, TN

The following registrations were revoked for being guilty of dishonorable, immoral, unethical, or unprofessional conduct; failure to comply with a lawful order or duly promulgated rule of the board; engaging in conduct prohibited or made unlawful by any of the provisions of TCA Title 63, Chapter 10, Parts 2-5, or any other state or United States laws relating to drugs or to the practice of pharmacy; failure to adhere to rules and/or statutes, as follows: possessed legend drugs without a valid prescription and outside of the supervision, control, or responsibility of a pharmacist; and/or to wit: removed legend drugs from pharmacy without authorization.

- ◆ **Robin Lea Hayes, RT**, Marion, AR
- ◆ **Evelyn Annette Haynes, RT**, Franklin, TN
- ◆ **Kara Lea King, RT**, Franklin
- ◆ **Jessie Elizabeth Smith, RT**, New Market, TN
- ◆ **Jessica Faith Turner, RT**, Gallatin

The following registrations were revoked or surrendered for engaging in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of this chapter or any other state or United States laws relating to drugs or to the practice of pharmacy.

- Elizabeth Nicole Mays, RT**, Cross Plains, TN
- Laresha L. Phillips, RT**, Nashville
- Kayla Marie Stedam, RT**, Lansing, TN – Voluntarily surrendered.
- Bethany Johnson Robbins, DPh**, Columbia, TN – License placed on probation for 10 years; assessed \$5,000 civil penalty, plus costs not to exceed \$10,000.

Other November 2015 violations include the following:

- Robert L. Fannon, DPh**, LaFollette, TN – Failed to provide patient counseling; assessed \$1,000 civil penalty.
- Aaron R. Flinchum, DPh**, Hiwassee, VA – Found guilty of dishonorable, immoral, unethical, or unprofessional conduct; failure to comply with a lawful order or duly promulgated rule of the board; failure to adhere to rules and/or statutes, as follows: a pharmacist shall hold the health and safety of patients to be the first consideration and shall render to each patient the full measure of the pharmacist’s ability as an essential health practitioner. He was placed on probation for one year; must also complete 10 hours of continuing education (CE) in immunization.

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: isminfo@ismp.org.

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been

FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each



vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at www.fda.gov/Safety/Recalls/ucm464071.htm.

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at www.fda.gov/Safety/Recalls/ucm464072.htm.

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public

when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanyl. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at www.fda.gov/Drugs/DrugSafety/ucm458952.htm.

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at www.fda.gov/Safety/Recalls/ucm461939.htm.

Christi Jacobi, DPh, Dyersburg, TN – All licenses and certificates of registration shall be renewed on or before the last day of the two-year cycle; failed to comply with a lawful order or duly promulgated rule of the Board and was assessed \$600 civil penalty.

Jeremy Jay Joiner, DPh, Nashville – Found in violation of being addicted to the use of alcohol, narcotics, or other drugs; exhibited an incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, confidence, and safety to the public; and found guilty of dishonorable, immoral, unethical, or unprofessional conduct. He voluntarily surrendered his license.

Madison Pharmacy, Inc, Pharmacy #3957, Memphis – Only pharmacists practicing at the pharmacy and pharmacists authorized by the pharmacist-in-charge shall be in possession of any keys or other access devices; assessed \$100 civil penalty.

Mark's Pharmacy, Inc, Pharmacy #1352, Rocky Top, TN (formerly Lake City, TN) – Failed to adhere to rules and/or statutes as follows: as a compounding pharmacy failed to operate in compliance with Tennessee laws governing the practice of pharmacy. The license was placed on probation for 90 days with terms.

Riggs Drugs, Pharmacy, LaFollette – Failed to provide patient counseling. The pharmacy was assessed \$1,000 civil penalty and must submit to the Board an acceptable, store-specific, corrective plan of action that addresses the failure to counsel in accordance with Rule 1140-3-.01.

December 2015

The following registrations were suspended for failure to pay student loans.

- ◆ **Lumeka Lewis, RT**, Goodlettsville, TN
- ◆ **Rachel E. Marek, RT**, Sewanee, TN
- ◆ **Konia McCord, RT**, Cookeville, TN
- ◆ **Amy Phillips, RT**, Livingston, TN
- ◆ **Teresa Ann Santana, RT**, Lebanon, TN
- ◆ **Lynda M. Thacker, RT**, Knoxville
- ◆ **Cathleen K. Ware-Pilgrene, RT**, Clarksville, TN
- ◆ **Darryl J. Woodfolk, RT**, Clarksville

The following violation was also reported:

Brittany Lindsey, RT, White House, TN – Received a criminal conviction and was granted a conditional license with terms.

New Information for Tennessee Pharmacy Registrants Reporting Theft or Loss to DEA

Per Title 21, Code of Federal Regulations, Section 301.76(b), registrants must notify their local Drug Enforcement Administration (DEA) office, in writing, of the theft or significant loss of controlled substances within one business day of discovery. Tennessee registrants may now satisfy this requirement by submitting all relevant information via email to tntheftorloss@usdoj.gov. Registrants must still complete a DEA Form 106 online via the DEA website, www.deadiversion.usdoj.gov. If you have questions, please contact Diversion Investigator James N. Stevens at 615/736-7343.

State's Audit Report of Board and Controlled Substance Database Committee Available for Review

On October 25, 2016, the state of Tennessee Comptroller of the Treasury Division of State Audit prepared an audit regarding the Board's activities, inspections benchmarks, and management responsibilities from January 2, 2011, to December 31, 2014. The Controlled Substance Database Committee management was also audited. The complete report may be viewed [here](#).

Board Reminders

At its November 2015 meeting, Board members decided that if registrants wish to request a waiver of rule, they should attend the Board meeting in the event questions arise that may not otherwise be answered from the written request. If you have requested a waiver and have not heard from the Board office as to when your request will appear on the agenda, you are advised to send an email to Board Administrator Sheila Bush at sheila.bush@tn.gov or contact the Board office at 615/253-1299.

Also, Board Executive Director Reginald B. "Reggie" Dilliard, DPh, reminds registrants that dispensers **are now required to report to the Controlled Substances Monitoring Database every business day** as stated in TCA 53-10-305(b) (emphasis added):

A pharmacy dispenser that uses a computerized system to record information concerning the dispensing of controlled substances listed in Schedule II, III, or IV, and Schedule V controlled substances identified by the controlled substance database advisory committee as demonstrating a potential for abuse, shall submit the required information to the committee or its agent utilizing nationally recognized pharmacy telecommunications format standards by a procedure and in a format established by the committee **for each business day but no later than the close of business on the following business day . . .**

This part of the statute became effective after January 1, 2016. For more information, click [here](#).

Moreover, Dr Dilliard reminds all sterile compounding pharmacy owners that the compounding modifier fee is required. All sterile compounding/manufacturing sites should now have paid their fees and should keep their letter, sent from the Board office, as proof of payment for the Board investigator's review. Please follow this [link](#) to add this modifier if applicable.

To Dispense Buprenorphine or Not – That Is the Question

Buprenorphine dispensing questions continue to be a hot topic and the Board recently received the following question.

Can buprenorphine patches (ie, Butrans®) be dispensed for addiction?

Dr Dilliard's response: If a physician writes a prescription for Butrans for addiction, it is **not** approved for such and should **not** be dispensed. If written for pain, then it may be dispensed. If a physician writes a prescription for Suboxone® for pain, it should **not** be dispensed. If for addiction, it may be dispensed. **The law states that it must be prescribed only for Food and Drug Administration-approved indications.** The use of an X number (referring to the prescribing practitioner's DEA number) only applies to those physicians who have been approved under the Drug Addiction Treatment Act-waived provisions to treat patients

for outpatient **addiction** and is not required for the treatment of pain. Any physician may use Butrans for pain. I know it can be confusing, but the X number was only brought into play to indicate that the physician treating **addiction** had the proper training to do so. More information will be included in the Spring Board of Pharmacy Updates, found at www.uthsc.edu/pharmacy/ce.

Board Members Are Elected to New Leadership Roles

At the January 12, 2016 meeting, with another year completed, Dr Nina Smothers handed the gavel to incoming Board President Dr William J. Bunch. Dr Kevin Eidson accepted the vice president position, as both nominees were elected with a unanimous vote from the Board.

With a few words of gratitude, Dr Bunch explained that Smothers had gone “above and beyond the call of duty” in her role as Board president.

“She played a big role in the gap analysis, and she had a lot to do with our interview process with our Executive Director, Dr Dilliard,” said Bunch.

Dr Smothers responded in appreciation: “It has been an honor and a humbling experience to work as president and just a very rewarding time from my life as a pharmacist. I am very grateful to have had that opportunity, and hope in some small way, that I have made a contribution to the profession overall.”

Dr Dilliard also responded: “It has been my pleasure to work with Nina this year,” and stated that Smothers had performed an admirable job as president and moved the meetings forward “each and every time.” He added, “We’ll certainly miss her when it comes time for her to move on.”

New Board Member Appointed

As she has accepted an appointed position from Governor Bill Haslam, the members of the Board invite Dr Rissa Pryse to take a seat at the table for the latest discussions of Tennessee pharmacy rule and regulation.

Dr Pryse is married to physician John Burrell, and has four daughters: Raewyn Snodderly, PharmD, Leslie Stanley, Elizabeth Tamer, and Emily Tamer.

Dr Pryse received her doctor of pharmacy degree in 1980 from the Mercer University Southern School of Pharmacy in Atlanta, GA, and started work at Terry’s Pharmacy, located in LaFollette. She purchased that pharmacy soon after and has added another, located in Jacksboro, TN.

Dr Pryse is a member of several pharmacy-related associations including the National Community Pharmacists Association, the Tennessee Pharmacists Association (serving as a current House of Delegates member for the Tennessee Society of Independent Pharmacists), Tennessee Valley Pharmacists Association, and the Professional Compounding Centers of America. She is a preceptor for the University of Tennessee Health Science Center College of Pharmacy, South College School of Pharmacy, and Samford University McWhorter School of Pharmacy in Birmingham, AL. Dr Pryse is certified to administer immunizations and provide medication therapy management.

While not working in the pharmacy, Dr Pryse attends the LaFollette United Methodist Church where she served on the Board of Trustees from 2011 to 2014. She is a member of the Rotary Club, Chamber of Commerce, Republican Committee, Women’s Domestic Violence Board, and the E911 Board, all

representing Campbell County. The Board looks forward to her input regarding retail and compounding experience. Welcome aboard, Dr Pryse!

Help Is Available for Impaired Pharmacists Through the Tennessee Pharmacists Recovery Network

If you need help or know an associate who does, please contact Baeteena Black, Tennessee Pharmacists Recovery Network program director, by phone at 615/256-3023 or by email at bblack@tnpharm.org.

An information link (including the reporting form) is located at www.tnpharm.org/member-center/tn-pharmacists-recovery-network.

Board Meeting Schedule

The Tennessee Board of Pharmacy extends an open invitation for all registrants and the general public to attend its public meetings at 665 Mainstream Drive, Nashville, TN 37243. The meetings are currently scheduled to begin at 9 AM. Pharmacists may receive up to two hours of live CE, valid for their Tennessee pharmacist license, on a full meeting day, and one hour on a half-day. As always, check for schedule changes on the Board website under the “Meeting Schedule” tab.

Currently, the **2016** meeting schedule is listed as follows: March 8-9, May 10-11, July 26-27, September 20-21, and November 8-9.

Mandatory Practitioner Profiles

The Board reminds licensees that the Mandatory Practitioner Profile Questionnaire for Licensed Health Care Providers must be completed and updated as information changes. To obtain a copy of the Mandatory Practitioner Profile Questionnaire, visit <http://tn.gov/health/article/pharmacy-applications> and click on “Mandatory Practitioner Profile Questionnaire (PH-3585).”

Completed/updated profiles should be submitted by mail to the Tennessee Department of Health, care of the address provided as part of the questionnaire instructions.

Tennessee Board of Pharmacy Members

- Dr William J. Bunch – President
- Dr Kevin Eidson – Vice President
- Dr Mike Dickenson – Board Member
- Dr Debra Wilson – Board Member
- Dr Rissa Pryse – Board Member
- Dr Nina Smothers – Board Member
- Ms Joyce McDaniel – Public Board Member

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